Technical Specifications of Fibroscan (Hepatic Elastography)

1. Description of function: Device will be used to measure stiffness or elasticity of hepatic parenchyma, spleen fibrosis diagnostic system and quantification of steatosis with ultrasonic attenuation of liver by completely non-invasive procedure.

2. Device should be able to measure liver stiffness and steatosis simultaneously during one single examination for adults and paediatrics populations without any restriction on age, with any kind of morphology (including patients with obesity).

3. It should operate on Vibration Controlled Transient Elastography technology with a fixed and controlled shear wave frequency (50Hz).

4. The unit should have a dedicated Spleen Stiffness measurement module which should compute Spleen Stiffness with a controlled shear wave frequency of 100Hz. It should be able to perform spleen examination on all adult patients.

5. The unit should be able to measure Spleen stiffness from 6.0 kPa to 100 kPa with the measurement depth of 25mm to 55mm.

6. The unit should have a 2D Convex Ultrasound guidance transducer of 2 to 3 MHz frequency to help localize Liver and Spleen.

7. Device should be BIS/European CE / USFDA certified and valid certificate must be attached with bid document.

8. It should be able to measure liver stiffness from minimum 2.0 kPa to 75kPa. It should be able to measure controlled attenuation parameter from minimum 100 dBm (decibels per metre) to 400dB/m.

9. Machine should be able to perform liver stiffness, quantification of steatosis for diagnosis of Alcoholic or Non-Alcoholic steatohepatitis, or Metabolic Associated Steatotic Liver Disease (ASH or NASH or MASLD).

10. Technology must be provided with additional diagnostic tools, such as Scores, combining device measured parameters (liver stiffness, CAP) with circulating biomarkers to support management and clinical decisions on patients with MASLD.

11. Machine with in-built cart must be easily moveable, full swivel, lockable wheels and total weight of the machine with one standard probe and accessory must be less than 50 Kg. Device must have a easily wipeable (with lock feature) integrated key board.

12. Device must have an integrated bar-code reader for faster patient workflow.

13. It should have LCD display of not less than 19 inches color touch screen having wide viewing angle.

14. Device must provide guidance to clearly identify the optimal measurement location in the liver through continuous vibration of the probe.

15. The machine should have facility of measuring Continuous CAP with a minimum of 200 attenuation readings during the examination phase. It should also enhance depth measurement for both the probes suitable for adult and obese patients.

16. Device must be able to switch between a minimum of two connected transducers, and provide a live guidance on the probe type to use depending on the patient body type.

17. Device must have automated and fixed examination parameters for the optimal measurement depth (automated selection of the region of measurement and of the measurement depth), this should be independent from the operator.

18. Device must have automated quality control features to include: probe force indicator, liver stiffness and CAP indicators, and automated rejection of invalid measurements for Liver stiffness.

19. Device must display relevant Inter Quartile Range (IQR) versus Median liver stiffness ratio (%) and Standard Deviation for CAP measurements to ensure exam quality can be easily assessed.

20. Device must have the ability to automatically trigger 10 valid individual measurements based on the quality indicators (probe force indicator, liver stiffness indicator, CAP™ indicator) through a single click.

21. Probes should be calibrated once in a year or as and when suggested by the machine.

22. The machine should work on AC Mains 220V, 50-60Hz.

23. It should have following connectivity facilities:

    a) Ethernet

    b) two or more no. of USB 2.0 ports

    c) two no. of probe connectors

24. Device must be able to export data under different formats (PDF, .xls, .jpg) and must have a sufficient storage capacity to save a minimum of 25,000 examination records on the device archive.

25. Probe properties and features should be as below:

a) Standard Probe

Type	: For adults from 14 years age onwards
Usage	: To measure Hepatic stiffness and steatosis
Metrological performance	: probe transducer central frequency 3.5 MHz
Measurement depth	: minimum 25 to 65 mm
Mechanical properties	: Dimension – 158 x 52 mm (L x diameter)
Weight of probe	: not more than 500 Grams
Transducer Diameter	: should not be more than 7 mm

b) Obese Patient Probe

Type	: For Obese Patient
Usage	: To measure Hepatic stiffness and steatosis
Metrological performance	: probe transducer central frequency 2.5 MHz
Measurement depth	: minimum 35 to 75 mm
Mechanical properties	: Dimension – 158 x 52 mm (L x diameter)
Weight of probe	: not more than 500 Grams
Transducer Diameter	: should not be more than 10 mm

c) Paediatric Probe

Type	: For Paediatric patient
Usage	: To measure Hepatic stiffness and steatosis
Metrological performance	: probe transducer central frequency 5 MHz
Measurement depth	: minimum S1:15 to 40 mm & S2: 20 to 50 mm
Mechanical properties	: Dimension – 158 x 52 mm (L x diameter)
Weight of probe	: not more than 500 Grams
Transducer Diameter	: should not be more than 5 mm

26. Device should be quoted and supplied with 5 years warranty and thereafter 5 years CMC.

27. Accessories required to operate the system.

Computer system- Qty.01 No. with minimum 21" color TFT Monitor, key board, mouse and UPS of 20 min or more power backup.
Colour ink-jet Printer.
Ultrasound Jelly- 250 ML Tube/ Bottle x 10 number.